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(71) Applicants and
(72) Inventors: ASHWORTH, Andrew, John [GB/GB]; 22 Springfield, South Queensferry, West Lothian EH30 9XD (GB). ASHWORTH, Lorna, E., B. [GB/GB]; 22 Springfield, South Queensferry, West Lothian EH30 9XD (GB).

(74) Agent: MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G4 8QA (GB).

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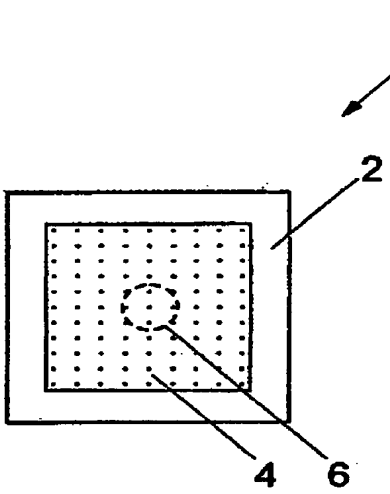
(54) Title: APPARATUS AND METHOD FOR ADMINISTRATION OF MEDICATION

(57) Abstract: Apparatus and method for the mucosal administration of medication .The apparatus has a vehicle adapted for delivery of said medication. The vehicle is retrievable after use to allow a supervisor to ensure that the medication has been correctly administered and to prevent misuse of any unadministered drug. Typically the vehicle is adapted to be retrievable substantially intact after delivery.



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Apparatus and Method for Administration of Medication

This invention relates to an apparatus and method for administration of medication.

Opiate/opioid addicts may be treated by controlled administration of substitute medication. Some such substitute medication is normally administered by mucosal route under supervision. However such medication has more potent effect if injected or "snorted". There is also a thriving black market for such medication. It is relatively simple for a patient to divert such medication for alternative use or resale, even when it is administered under supervision.

According to the present invention there is provided an apparatus for the mucosal administration of medication comprising a vehicle adapted for delivery of said medication.

Said vehicle may be retrievable after use. Typically said vehicle is adapted to be retrievable substantially intact after delivery.

Preferably said vehicle is adapted to enclose said medication. Additionally or alternatively said vehicle may be adapted to be impregnated with said medication.

Said vehicle may be adapted to fit in the mouth. Said vehicle may be adapted to fit under the tongue.

Preferably said vehicle is comprised of material inert to saliva. More preferably said vehicle is comprised of material permeable to saliva.

Typically said vehicle comprises a permeable container.

Preferably said container is adapted to receive medication during its manufacture.

Said container is preferably adapted to accommodate medication in solid form. Said solid form may comprise a tablet. Said solid form may comprise a frozen liquid.

Preferably said container is sealed. Alternatively said container is adapted to be sealed.

Further according to the present invention there is provided a method of administration of medication comprising the steps of:
including said medication in a vehicle;
supervising a patient while the vehicle is placed in a patient's mouth;

waiting until the contents of the vehicle have been absorbed into the patient's bloodstream;
reclaiming the vehicle; and
ensuring the vehicle is intact.

Preferably said method comprises the step of sealing said medication within a permeable container. More preferably said method comprises the step of sealing said medication within a permeable container during manufacture of said container.

Embodiments of the present invention will now be described by way of example only with reference to the accompanying drawings in which:

Fig 1 is a permeable container in accordance with an aspect of the invention; and

Fig 2 is a permeable container in accordance with a further aspect of the invention.

Referring to the drawings, an apparatus for the mucosal administration of medicament comprises a vehicle 1 in the form of a container 2, 3 substantially of permeable material. The container 2, 3 is manufactured of material that is permeable to saliva, and that does not react with saliva.

In the embodiment illustrated in Fig 1, the container 2 comprises a sealed pouch 4 of permeable material. Medication 6 is placed within the pouch 4 during manufacture of this container 2, and the pouch 4 is

then sealed. The medication is thus contained within the sealed pouch.

In the embodiment illustrated in Fig 2, the container 3 comprises a pouch 8 with an opening 10, wherein the opening 10 is adapted to be sealed. The opening 10 permits inclusion of a medicament. In this embodiment the pouch 8 is substantially of material that contains a percentage of nylon. The edges of the opening 10 of the pouch can be fused by heat sealing once a medicament is placed therein.

Each vehicle 1 comprises a unique identifier to prevent its substitution.

This vehicle 1 is useful in administration of opiate/opiod medication to patients.

An example of appropriate patients would be recovering drug addicts. There is always the temptation for such patients to attempt to divert the medication for later more potent use or resale. For this reason, the medication is administered under supervision.

The medication is normally in tablet form and adapted to be delivered by mucosal route. That is, the medicament is designed to be absorbed under the tongue or elsewhere within the mouth. Tablets used for this purpose are small and easily hidden.

The administrator presents tablets to the patient in the sealed container 2,3 of the invention, which he

then retrieves - still sealed - when empty. This allows the administrator to be satisfied that the contents of the container 2,3 have been absorbed into the bloodstream of the patient, and not diverted for other purposes.

That is, since the vehicle 1 is recoverable intact, there is a great degree of confidence that the medication has been properly administered to the intended patient.

The vehicle 1 of the instant invention also allows administrators of medication to reduce the possibility of diversion of medication with black market resale value if it becomes a requirement that a repeat prescription is only available on return of intact containers 2,3. This will reduce the likelihood of diversion of such medication for sale, for example by pensioners.

In a further embodiment the structure of the vehicle 1 is impregnated with the medicament; or impregnated with or made from material that reacts with medication accommodated in the container 2,3 on dispensing.

The vehicle 1 also has application in administration of drugs to unconscious or disabled patients. The size, shape or nature of the vehicle 1 is adapted to prevent inadvertent inhalation or swallowing of the vehicle 1.

For this purpose, the vehicle 1 has a portion adapted to protrude from the mouth when it is in position. The

protruding portion operates as a handle, allowing an administrator to retain control of the vehicle 1, and allowing easy removal of the spent vehicle 1 from a patient's mouth. In one embodiment, the protruding portion is a string or cord.

Details concerning the contents of the vehicle 1, for example the dosage or patient's name or a serial number or date, can be printed and displayed or otherwise included on the surface of the material that comprises the vehicle 1.

The vehicle 1 can be impregnated with, or otherwise contain a pH indicator. That is, the vehicle 1 can be customised for specific purposes.

The container 2, 3 will accommodate medication in tablet form, or in any solid form such as a frozen liquid.

In the embodiments of Figure 1 and Figure 2, the container 2,3 is soft and porous, and resembles a teabag. The material from which teabags are manufactured is ideal for this vehicle 1. In use, medication 6 in tablet form is enclosed within this container 2,3. The medication 6 is either sealed in the container 2 during its manufacture, or the container 3 is filled and sealed by or on behalf of the administrator. Each vehicle 1 contains a unique identifier, such as a serial number.
The sealed container 2,3 is dispensed to the patient. The patient is observed while he places the container

2,3 in his mouth or under his tongue, for the period during which the medication is dissolving and being absorbed, and as he removes the empty container 2,3 from his mouth.

The administrator can then use the unique identifier to satisfy himself that there has been no replacement of containers 2,3 during this process. If this is the case, the administrator can then examine the container 2,3 to satisfy himself that the container 2,3 has not been tampered with, and remains intact.

The container 2,3 can also be made of material that is designed to dissolve, but at a rate slower than that of the medication it is adapted to contain. The surface of the vehicle 1 can be impregnated with medication.

In one embodiment, the vehicle 1 comprises a piece of material impregnated with a medicament. This embodiment of the vehicle 1 does not require to be sealed, but is still retrievable intact by the administrator.

A further embodiment of the vehicle 1 comprises a container 2,3 the surface of which can be impregnated with material that changes the properties of the medication contained in the container 2,3 on dispensing.

The vehicle 1 can be used to administer medication to unconscious patients, and to monitor its absorption.

The vehicle 1 has application in administering medication to patients who require supervision to ensure that the medication is taken, such as geriatric and paediatric patients. The vehicle 1 can be coloured, flavoured, patterned or otherwise decorated to make more palatable to children.

The vehicle 1 has further application for veterinary use.

The common features of all embodiments of the vehicle 1 are that they remain intact throughout the procedure of administration of medication, and are retrievable for scrutiny after administration to confirm that medication has been appropriately administered.

Improvements and modifications can be made to the above without departing from the scope of the invention.

CLAIMS

1. Apparatus for mucosal administration of medication comprising a vehicle adapted for delivery of said medication.

2. Apparatus as claimed in claim 1, wherein said vehicle is retrievable after delivery.

3. Apparatus as claimed in either preceding claim, wherein said vehicle is adapted to be retrievable substantially intact after delivery.

4. Apparatus as claimed in any preceding claim, wherein said vehicle is adapted to enclose said medication.

5. Apparatus as claimed in any preceding claim, wherein said vehicle is adapted to be impregnated with said medication.

6. Apparatus as claimed in any preceding claim, wherein said vehicle is adapted to fit in the mouth.

7. Apparatus as claimed in any preceding claim, wherein said vehicle is adapted to fit under the tongue.

8. Apparatus as claimed in any preceding claim, wherein said vehicle is comprised of material inert to saliva.

9. Apparatus as claimed in any preceding claim, wherein said vehicle is comprised of material permeable to saliva.

10. Apparatus as claimed in any preceding claim, wherein said vehicle comprises a permeable container.

11. Apparatus as claimed in Claim 10, wherein said container is sealed.

12. Apparatus as claimed in Claim 10, wherein said container is adapted to be sealed.

13. Apparatus as claimed in any preceding claim, wherein said container is adapted to receive medication during its manufacture.

14. Apparatus as claimed in any preceding claim, wherein said container is adapted to accommodate medication in solid form.

15. Apparatus as claimed in Claim 14, wherein said solid form comprises a tablet or said solid form comprises a frozen liquid.

16. Method for administration of medication comprising the steps of:
including said medication in a vehicle;
supervising a patient while the vehicle is placed in a patient's mouth;

waiting until the contents of the vehicle have been absorbed into the patient's bloodstream; reclaiming the vehicle; and ensuring the vehicle is intact.

17. Method as claimed in claim 16, wherein the method further comprises the step of sealing said medication within a permeable container.

18. Method as claimed in either of claims 16 or 17, wherein the method further comprises the step of sealing said medication within a permeable container during manufacture of said container.

19. Apparatus for mucosal administration of medication substantially as hereinbefore described with reference to the accompanying drawings.

20. Method for administration of medication substantially as hereinbefore described with reference to the accompanying drawings.

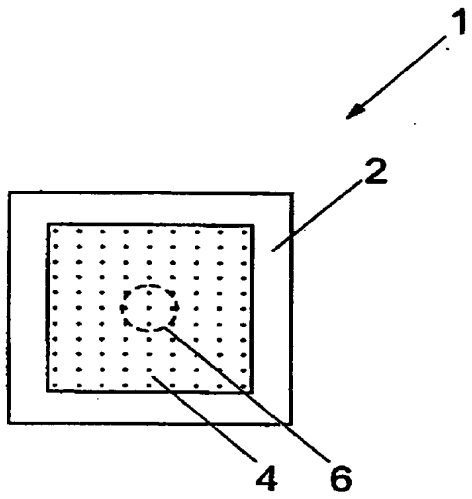

Fig. 1

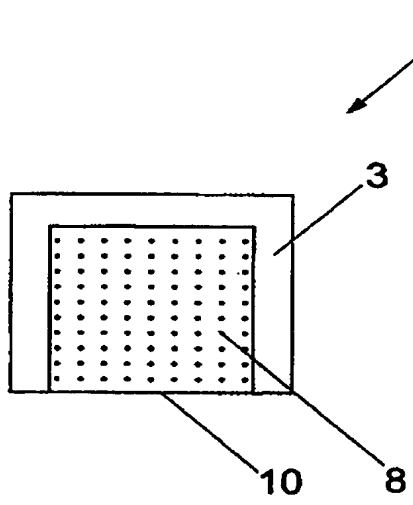

Fig. 2

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61J7/00 A61J1/03 A61K9/70

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61J A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 167 244 A (KJERSTAD RANDY E) 1 December 1992 (1992-12-01) column 5, line 14 - line 26 column 5, line 50 - line 57; figures	1-14, 17-20
X	WO 91 03271 A (UNIV UTAH RES FOUND) 21 March 1991 (1991-03-21) page 22, line 3 - line 11; figures 1-16	1-10,14, 15,19,20
X	US 3 948 254 A (ZAFFARONI ALEJANDRO) 6 April 1976 (1976-04-06) column 4, line 41 - line 47 column 20, line 24 - line 38; figures 1-5	1-10,14

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 November 2000	16/11/2000
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INTERNATIONAL SEARCH REPORT

information on patent family members

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